1615 IHW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	SAHIN et al.	
Serial No.:	10/537,002	Art Unit: 1615
Filed:	May 20, 2005	Examiner: (not yet assigned)
Entitled:	GENETIC PRODUCTS DIFFERENTIALLY EXPRESSED IN TUMORS AND THE USE THEREOF	

Attorney Docket No.: GMD-102.1P US

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION TO MAKE SPECIAL
PURSUANT TO 37 C.F.R. §1.102(b)

Invention Contributing to the Diagnosis, Treatment, or Prevention of Cancer

Sir:

This petition to make special is submitted pursuant to 37 C.F.R. §1.102(b) based on the present inventions' expected contribution to the diagnosis, treatment and/or prevention of cancer. A check in the amount of $130.00 {check no. 6716} in payment of the fees under 37 C.F.R.§1.17(h) is enclosed herewith. No additional fees are believed to be due; however, the Commissioner is specifically authorized to charge any additional fees deemed to be necessary in connection with the filing of this paper to Deposit Account 50-0268.

12/13/2005 EFLORES 00000039 10537002
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REMARKS

Pursuant to 37 C.F.R. §1.102(b), Applicants hereby request advancement of examination of the present application based on present inventions' expected contribution to the diagnosis, treatment and/or prevention of cancer. MPEP §708.02(X).

Introduction

The present application is assigned to Ganymed Pharmaceuticals AG, which is in the business of discovering tumor-specific antigens and developing effective immunotherapies targeting these antigens. Ganymed is developing anti-cancer antibodies, T cell receptors, vaccines, diagnostics, siRNA and small molecules that are directed at targets that are both cancer-specific and present in numerous cancer types.

By way of analogy, a non-limiting element of the discovery of the present invention is similar to those discoveries made leading to the now well-known anti-cancer antibody drugs Rituxan® and Herceptin® (*see, e.g.*, www.rituxan.com and www.herceptin.com). These biologic therapies are based on antibodies that selectively bind to particular antigens presented on cancerous cells, whereby they may block tumor cell growth and/or target the cell for destruction by the immune system. While both Rituxan® and Herceptin® have advanced the art and made significant contributions to the detection and treatment of non-Hodgkin's lymphoma and metatastic breast cancer, these molecules, like most of the antibodies in clinical development for cancer, are aimed at poorly differentiated or partially selective targets present only in a small minority of a particular cancer type. Moreover, the targets of these and other antibody drugs are often expressed (in lesser amounts) in normal tissues. Thus the likelihood of adverse side-effects severely limits the therapeutic potential of many candidate cancer drugs. In other words, there remains a persistent need for new and improved cancer therapies.

Applicants' Discovery

Applicants set out to identify candidate targets that are expressed virtually only in cancer tissue and not in normal tissue. Therapies to these targets would likely have much greater therapeutic utility than target-specific drugs currently on the market.

Using these guidelines, Applicants discovered it was possible to detect differential glycosylation for Claudin-18 in tumors (*see, e.g.*, page 9, lines 10-23, and Example 4 spanning pages 92-99 of Applicants' specification). Applicants found that gastrointestinal carcinomas, pancreatic carcinomas, esophageal tumors, prostate tumors as well as lung tumors have a form of Claudin-18 which is *glycosylated at a lower level*. This is significant because glycosylation in healthy tissues

masks (blocks) protein epitopes (*i.e.*, therapeutic targets) of Claudin-18. These same protein epitopes are exposed, *i.e.*, not blocked by glycosylation, in tumor cells, and therefore it is possible to select ligands and antibodies that bind to these domains. These ligand and antibody pharmaceuticals stemming from Applicants' discovery are *therapeutically selective*, that is, they do not bind to Claudin-18 on healthy cells because the same epitopes are masked by normal glycosylation.

The target expression results obtained by Ganymed so far indicate that appropriate targeted tumor therapies would be significantly better than current therapies.

Based on the data disclosed in the application, Applicants submit that the present invention is expected contribute to the diagnosis, treatment, and prevention of cancer. Therefore, in accordance with 37 C.F.R. §1.102(b) and MPEP §708.02(X), Applicants hereby request advancement and acceleration of examination of the present application.

Respectfully submitted,

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Certificate of Mailing

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December 8, 2005
date


Nasim G. Memon

PTO/SB/17p (11-05)
Approved for use through 07/31/2007. OMB 0651-0031
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PETITION FEE
Under 37 CFR 1.17(f), (g) & (h)
TRANSMITTAL

(Fees are subject to annual revision)

Send completed form to: Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

Application Number	10/537,002
Filing Date	May 20, 2005
First Named Inventor	Ugur Sahin
Art Unit	1615
Examiner Name	(not yet assigned)
Attorney Docket Number	GMD-102.1P US

Enclosed is a petition filed under 37 CFR 1.102(b) that requires a processing fee (37 CFR 1.17(f), (g), or (h)). Payment of $ 130.00 is enclosed.

This form should be included with the above-mentioned petition and faxed or mailed to the Office using the appropriate Mail Stop (e.g., Mail Stop Petition), if applicable. *For transmittal of processing fees under 37 CFR 1.17(i), see form PTO/SB/17i.*

Payment of Fees (small entity amounts are NOT available for the petition fees)

☑ The Commissioner is hereby authorized to charge the following fees to Deposit Account No. 50-0268:
- ☐ petition fee under 37 CFR 1.17(f), (g) or (h)
- ☑ any deficiency of fees and credit of any overpayments

☑ Enclose a duplicative copy of this form for fee processing.

☑ Check in the amount of $ 130.00 is enclosed. (check no. 6716)

☐ Payment by credit card (Form PTO-2038 or equivalent enclosed). Do not provide credit card information on this form.

Petition Fees under 37 CFR 1.17(f): Fee $400 Fee Code 1462
For petitions filed under:
§ 1.36(a) - for revocation of a power of attorney by fewer than all applicants
§ 1.53(e) - to accord a filing date.
§ 1.57(a) - to accord a filing date.
§ 1.182 - for decision on a question not specifically provided for.
§ 1.183 - to suspend the rules.
§ 1.378(e) - for reconsideration of decision on petition refusing to accept delayed payment of maintenance fee in an expired patent.
§ 1.741(b) - to accord a filing date to an application under § 1.740 for extension of a patent term.

Petition Fees under 37 CFR 1.17(g): Fee $200 Fee Code 1463
For petitions filed under:
§ 1.12 - for access to an assignment record.
§ 1.14 - for access to an application.
§ 1.47 - for filing by other than all the inventors or a person not the inventor.
§ 1.59 - for expungement of information.
§ 1.103(a) - to suspend action in an application.
§ 1.136(b) - for review of a request for extension of time when the provisions of section 1.136(a) are not available.
§ 1.295 - for review of refusal to publish a statutory invention registration.
§ 1.296 - to withdraw a request for publication of a statutory invention registration filed on or after the date the notice of intent to publish issued.
§ 1.377 - for review of decision refusing to accept and record payment of a maintenance fee filed prior to expiration of a patent.
§ 1.550(c) - for patent owner requests for extension of time in ex parte reexamination proceedings.
§ 1.956 - for patent owner requests for extension of time in inter partes reexamination proceedings.
§ 5.12 - for expedited handling of a foreign filing license.
§ 5.15 - for changing the scope of a license.
§ 5.25 - for retroactive license.

Petition Fees under 37 CFR 1.17(h): Fee $130 Fee Code 1464
For petitions filed under:
§ 1.19(g) - to request documents in a form other than that provided in this part.
§ 1.84 - for accepting color drawings or photographs.
§ 1.91 - for entry of a model or exhibit.
§ 1.102(d) - to make an application special.
§ 1.138(c) - to expressly abandon an application to avoid publication.
§ 1.313 - to withdraw an application from issue.
§ 1.314 - to defer issuance of a patent.

Michael Wesolowski
Signature

12-8-05
Date

Michael R. Wesolowski
Typed or printed name

50,944
Registration No., if applicable

PTO/SB/21 (09-04)
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 6

Application Number	10/537,002
Filing Date	May 20, 2005
First Named Inventor	Ugur Sahin
Art Unit	1615
Examiner Name	(not yet assigned)
Attorney Docket Number	GMD-102.1P US

ENCLOSURES *(Check all that apply)*

- [x] Fee Transmittal Form
  - [x] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
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- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [x] Petition
- [ ] Petition to Convert to a Provisional Application
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- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
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- [ ] Other Enclosure(s) (please Identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

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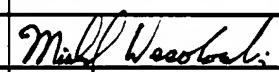
Signature			
Printed name	Michael R. Wesolowski		
Date	December 8, 2005	Reg. No.	50,944

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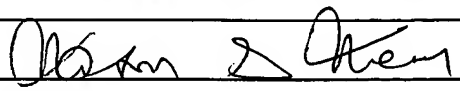
Signature			
Typed or printed name	Nasim S. Memon	Date	December 8, 2005